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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/848,439 05/08/97 LAVALLIE

E GI5288A

025291 HM12/1010
AMERICAN HOME PRODUCTS CORPORATION
FIVE GIRALDA FARMS
PATENT LAW
MADISON NJ 07940

EXAMINER

LINGAR, S

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

10/10/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/848,439

Applicant(s)

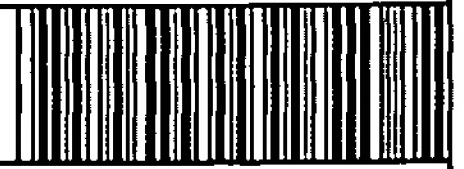
LaVallie et al

Examiner

Ungar

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1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 13, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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1. The Amendment filed August 21, 2001 (Paper No. 23) in response to the Office Action of February 13, 2001 (Paper No. 20) is acknowledged and has been entered. Claims 1-17 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Examiner's appreciates Applicant pointing out the inadvertent typographical error wherein Paper No. 20, Section 2, page 3 stated that claims "1, 2, 7 and 11 have been canceled". It is clear that the claims had been amended rather than canceled and that the Action on the Merits included examination of claims 1, 2, 7 and 11. Examiner apologizes for any inconvenience.
4. The following rejections are being maintained:

Claim Rejections - 35 USC § 101

5. Claims 1-17 remain rejected under 35 USC 101 for the reasons previously set forth in Paper No. 20, Section 5, pages 2-6.

Applicant argues that (a) Examiner has not established that it is more likely than not that a person skilled in the art would not consider credible any specific utility asserted by the applicant since Applicant's provide the nucleotide sequence of human SDF-5 and the protein encoded as well as methods of making the polypeptide encoded. Further, Applicants have provided art-recognized credible uses of SDF-5 proteins, (b) Examiner recognizes that the specification discloses utilities for SDF-5 including inducing formation/growth differentiation proliferation and/or maintenance of chondrocyte and/or cartilage tissue, (c) Examiner recognizes that the protein encoded by SEQ ID NO:1 is useful for binding Wnt protein and

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thus regulating the interaction of Wnt genes to receptor proteins, (d) the asserted utility is based on the homology of the SEQ ID NO:1 encoded protein to the Wnt binding domain of the extracellular binding domains of the Frizzled/Frazzled family, thus the skilled artisan can readily both make and use the SDF-5 proteins of the present invention, (e) Applicant discloses activity assays for SDF-5 thus the skilled artisan can readily determine the *in vivo* activities of Applicant's disclosed proteins, (f) the encoded protein is a novel member of a well recognized class of compounds with known activities, the Frazzled family, which are known to the art to be capable of activities including inducing formation/growth differentiation proliferation and/or maintenance of chondrocyte and/or cartilage tissue, thus the skilled artisan would consider Applicant's disclosed utilities both specific and substantial.

The arguments have been considered but have not been found persuasive (a') the disclosure of the polynucleotide sequence, amino acid sequence and a method for making the protein do not provide a specific utility for the claimed isolated DNA molecule for the reasons previously set forth, further for the reasons previously set forth, there is no art recognized credible use of the SDF-5 proteins, (b') Examiner does recognize that the specification discloses utilities for SDF-5 including inducing formation/growth differentiation proliferation and/or maintenance of chondrocyte and/or cartilage tissue however, this disclosure does not provide utility to the claimed invention for the reasons previously set forth, (c') contrary to Applicant's arguments, Examiner does not recognize that the protein encoded by SEQ ID NO:1 is useful for binding Wnt protein. However, Examiner

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does recognize that the specification discloses that the encoded protein **may** (emphasis added) be capable of binding the Wnt protein and thus **may** (emphasis added) be capable of regulating the binding interaction, (d') although the encoded protein may have homology to a Wnt binding consensus sequence, it is clear that it was unknown at the time the invention was made (see the specification, paragraph bridging pages 10-11) whether the encoded protein was capable of binding Wnt since the specification hypothesizes that the encoded protein **may be capable of binding Wnt proteins** (emphasis added). Further, Examiner made it clear that the activity of the murine SDF-5 was unknown and that differences between murine SDF-5 and frizzled proteins were known in the art and that differences in the expression pattern of mouse SDF-5 and the putative human homologue were clear and that in view of the teaching of Bork, and the lack of guidance in the specification, it is not possible to determine what SEQ ID NO:1 is or what it does. In addition, Examiner made it clear that the frizzled receptors which bind Wnt are likely to play multiple roles in vertebrate development and/or physiology and that there are more than a dozen Wnt proteins and that the specification does not teach which Wnt protein the encoded protein would be capable of binding nor which receptor binding interactions SDF-5 would be capable of regulating or which function, associated with the family, the encoded protein displays. Since no specific function has been identified with SDF-5, the protein encoded by SEQ ID NO:1, since SEQ ID NO:1 has not been shown to be associated with any specific disease, one of skill would not know how to use the invention, (e') Applicant invites the skilled artisan to elaborate a functional use for the disclosed nucleic

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acids, (f') the argument is not persuasive for the reasons set forth in (d') above and further, the cited utilities are neither specific nor substantial for the reasons set forth previously and above. Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

6. Claims 1-17 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 20, Section 7, page 6.

Applicant argues that because the claimed invention is supported by a specific utility for the reasons set forth above, one of skill in the art would know how to use the claimed invention. The argument has been considered but has not been found persuasive for the reasons set forth above. Applicant's arguments have not been found persuasive and the rejection is maintained.

7. No claims allowed.

8. **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE

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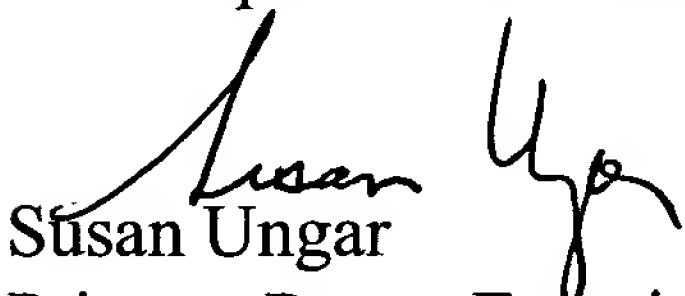
STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.


Susan Ungar
Primary Patent Examiner
October 7, 2001